REMARKS

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is being timely filed.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

In the present Amendment, claims 3 and 7 have been canceled without prejudice or disclaimer of the subject matter contained therein. Also, claims 1 and 6 have been amended. Thus, claims 1, 2, 4-6 and 8-11 are pending in the present application.

No new matter has been added by way of these amendments because each amendment is supported by the present specification. For example, the amendment to claim 1 has support throughout the present specification, including page 5, second full paragraph and page 6, second and fourth full paragraphs. Also, Applicants note that language appearing in the preamble in claim 1 has been moved to the body portion of the claims. With the cancellation of claim 3, the dependency of claim 6 has been appropriately amended. This is a clarifying and not a narrowing amendment. Thus, Applicants are in no way conceding any limitations with respect to the interpretation of the claims under the Doctrine of Equivalents.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §§ 102/103

There are several outstanding rejections cited under 35 U.S.C. § 102 and § 103(a) as stated on pages 2-8 of the Office Action. Applicants respectfully traverse and reconsideration is based on the following remarks.

In citing the various references, the Examiner explains that the heparans in the references appear to match the presently claimed heparans (see, e.g., page 2, regarding the rejection in view of Ellison *et al.* (2001)). Also, the Examiner states that the effects of the references' compounds appear to meet the functional limitation of the recited anticoagulant activity. Finally, the Examiner states that the USPTO does not have the facilities to determine any patentable differences between the compounds of the references and those presently claimed (see page 2 of the Office Action). In response, Applicants provide the following explanation.

The present invention is directed to a method for establishing effective labor in women by administering to a pregnant woman an effective amount of at least one sulfated glycosaminoglycan (see the Markush group recited in pending claim 1). The sulfated glycosaminoglycan has an anticoagulant activity of 100 BP units/mg or less to prophylactically prime or curatively treat the cervix and myometrium for the prevention or treatment of slow progress of term labor. The recited anticoagulant activity is not found in the cited references.

As stated in the specification at page 4, starting at line 8, the expression of heparan sulfate proteolycans have been recently found to vary during pregnancy and labor. Heparan and low molecular weight heparans (LMWH) have anticoagulant activity and are today indicated and used for the prophylaxis and treatment of thromboembolic disorders, also in pregnant women.

The use of traditional heparan, having an anticoagulant activity of >100 BP units/mg, involves a higher risk of bleeding and should be avoided during pregnancy.

The present inventors have found that the administration of low molecular weight heparans to pregnant women in need of thrombosis prophylaxis surprisingly has resulted in a faster progress of labor and a shorter delivery time. Based on said discovery, different sulfated glycosaminoglycans, also those lacking anticoagulant activity, have been tested in the laboratory and turned out to have similar effects.

Thus, the present invention refers to the use of sulphated glycosaminoglycans have an anticoagulant activity of 100 BP units/mg or less, preferably below 30 BP units/mg, to induce more effective labor in women. Today, clinical trials are performed at a number of Swedish maternity hospitals with sulphated glycosaminoglycans having a very low anticoagulant activity.[1]

Regarding the cited references, Applicants respectfully submit that all rejections have been overcome. None of the cited references even refer to the problem as solved by the present invention (e.g., improve the progress of labor in women). The cited references of Greinacher, Ellison, Sanson and Ginsburg all refer to antithrombotic treatment of pregnant women. This is a different treatment in that the treatment of the present invention is intended for another group of patients. Applicants note that the claims are directed to "A method for establishing effective labor in women." That is, the present invention is directed to women without any need of antithrombotic therapy, but having a problem with slow progress or arrest of labor at delivery.

[1] If a Declaration pursuant to 37 C.F.R. § 1.132 from the inventors is desired, the Examiner is requested to contact the Applicants' representative at the contact information given at the end of this reply.

The cited references conclude that the administration of low molecular heparans is not harmful to the baby, at least compared to heparan, and there is an advantage for the mother as to osteoporosis.

Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," none of the cited references of Greinacher, Ellison, Sanson and Ginsburg can be a basis for a rejection under § 102(b). *See Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, because of the lack of disclosure of all features as instantly claimed, the rejections under § 102 are overcome. Reconsideration and withdrawal are respectfully requested.

Regarding the § 103(a) rejections, one of the requirements for a *prima facie* case of obviousness is disclosure of all claimed features. *See In re Vaeck,* 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). That is not the case here. As mentioned, none of the cited references of Greinacher, Ellison, Sanson and Ginsburg discloses all claimed features. None of the other cited references discloses all claimed features as well (even in combination). Einarsson in the '477 patent discloses a pharmaceutical composition containing heparan derivatives, especially Fragmin, and glycerolesters to improve bioavailability. Laster in the EP '410 reference refers to treatment of pre-eclampsia with a mixture of glycosaminoglycans. There is no disclosure regarding improving the progress of labor or delivery in any of these references. Thus, a *prima facie* case of obviousness has not been established for any of the § 103(a) rejections and these rejections have been overcome.

Reconsideration and withdrawal of all rejections are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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